

Remarks/Arguments:

Claims 22 and 23, newly presented, and claims 1-13 and 16-21, previously of record, are pending.

Claims 1-13 and 16-21 stand withdrawn, pursuant to restriction.

Claims 14 and 15 are canceled, without prejudice or disclaimer.

New claim 22 corresponds to examined claim 14, amended by limiting the neurodegenerative disease to "Alzheimer's disease, or related diseases or disorders," by reciting (emphasis added) "whereby the modulator is modulating substances selected from the group consisting of," by limiting the Markush group of "substances" to the elected "translation product of a gene coding for a vault protein, the minor vault protein ADPRTL1 . . . and/or . . . derivatives thereof," and by clarifying that "ADPRTL1" has the amino acid sequence "as shown in SEQ ID NO: 2." ADPRTL1 corresponds to SEQ ID NO: 2, as disclosed in the subject application (page 11, second paragraph). New claim 23 contains the subject matter of new claim 22, using a different written format.

Claim 14 was objected to for reciting non-elected subject matter. Replacement claims 22 and 23 recite only the elected, "translation product" subject matter and, thereby, the objection is overcome. Withdrawal of the objection to claim 14 appears to be in order.

Claim 14 was rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Reconsideration is requested.

Actually, there are two rejections of claim 14 under §112, ¶2. The first rejection is overcome since replacement claims 22 and 23 do not recite, broadly, "neurodegenerative diseases."

Accordingly, the first rejection under §112, ¶2, is overcome. And, so, withdrawal of the rejection appears to be in order.

In the second rejection under §112, ¶2, the claim language "or related diseases or disorders of one or more substances selected from the group consisting of" allegedly rendered the claim indefinite. According to the statement of rejection it "is not clear [how] the phrase *of one or more substances selected from the group consisting of* is referring to a modulator of a neurodegenerative disease." New claim 22 recites "or related diseases or disorders whereby the modulator is modulating substances selected from group consisting of." In other words, the "modulator of Alzheimer's disease, or related diseases or disorders," sought by the claimed screening assay, also modulates (i.e., "is modulating") the "substances" having "the activity and/or level" measured according to the claimed assay. New claim 23 reflects the same changes (from claim 14) reflected in new claim 22, but in a different written format.

In view of the changes to claim 14 reflected in replacement claim 22 and 23, the second rejection under §112, ¶2 is overcome. Withdrawal of the rejection appears to be in order.

Claim 14 was rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. Reconsideration is requested.

Present replacement claims 22 and 23 both limit the substance—having the "activity and/or level" measured in each of the test-compound-containing cell and the control cell—to the "translation product" of the gene encoding "protein ADPRTL1" and a derivative thereof. Moreover, the protein is, now, identified as that protein having the sequence SEQ ID NO: 2. Accordingly,

applicants submit that the rejection under §112, ¶1, is overcome and withdrawal of the rejection appears to be in order.

Claim 14 was rejected under 35 USC 102(b) for being allegedly anticipated by Rome (WO 99/62547). Reconsideration is requested.

Rome discloses human minor vault protein p193—minor vault protein ADPRTL1, by a different name. The reference also discloses a method of diagnosing multidrug-resistant cancer.

Present claims 22 and 23, which replace claim 14, are limited to the diagnoses of Alzheimer's Disease. Multidrug resistance is the ability of pathologic cells to withstand chemicals that are designed to aid in the eradication of such cells. Such pathological cells include cancer cells, since some cancer cells have the ability to become resistant to multiple, different drugs (e.g., antineoplastic drugs and anticancer drugs). Such cancer cells are, thus, referred to as being multidrug-resistant.

Cancer cells, whether or not multidrug-resistant, are completely irrelevant for Alzheimer's Disease. Alzheimer's Disease, or a disease or disorder related to Alzheimer's disease, is very different from multidrug-resistant cancer, as readily apparent to one of ordinary skill in the art.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "identically appear" in the

reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

As explained, above, Rome discloses nothing, whatsoever, in connection with Alzheimer's disease, or a related disease or disorder. The "absence" from Rome of the claim limitation "screening for a modulator of Alzheimer's disease, or a related disease or disorder," "negates anticipation" by Rome of either present claim 22 or present claim 23. *Kolster Speedsteel A B*, 230 USPQ at 84. Withdrawal of the rejection appears to be in order.

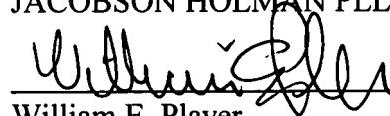
Furthermore, Rome cannot be considered as being a promising spring board for a person skilled in the art to arrive at the presently claimed invention. The person skilled in the art could not have drawn any inferences, with respect to Alzheimer's disease, from observations pertaining to multidrug-resistant cancer—a pathological disorder totally different from Alzheimer's disease.

Favorable action is requested.

Respectfully submitted,

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